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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,368	06/28/2001	David M. Allen	P1067	2222

7590 11/17/2004

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EXAMINER

PAK, JOHN D

ART UNIT PAPER NUMBER

1616

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/896,368	<b>Applicant(s)</b> ALLEN, DAVID M.	
	<b>Examiner</b> JOHN PAK	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 8-10 and 12-42 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 8, 9, 18-32 and 38-42 is/are allowed.
- 6) ☒ Claim(s) 10, 12-14, 33 and 34 is/are rejected.
- 7) ☒ Claim(s) 15-17 and 35-37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Claims 1-3, 8-10 and 12-42 are presently pending in this application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 12, 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Chemical Abstracts 100:73895 for the reasons of record. See pages 6-7 of the last Office action (mail date: 2/27/2004) and pages 3-4 of the previous Office Action (mail date: 7/15/03).

Applicant's arguments relative hereto have been given due consideration but they were deemed unpersuasive. Applicant argues that the cited reference does not show use of an organic gel in an amount sufficient to enable a macrolide antibiotic to penetrate into musculoskeletal soft tissue." The Examiner cannot agree. First, applicant's originally filed disclosure is devoid of any teaching that specifies how much of the gel ingredient methyl cellulose should be present to provide such penetrating effect. Hence applicant's own disclosure suggests a broad range of such amount in the absence of specified criticality. Second, the cited reference here discloses erythromycin in an ointment base containing hydrogel of methyl cellulose with Tween 80, cetylstearyl alcohol and triethanolamine. Applicant's own specification discloses that organic

hydrogels are preferred and methylcellulose gel are suitable mobilizing agents (p. 6, lines 15-24). If hydrogels and methylcellulose gels are suitable as mobilizing agents in applicant's composition, the same methylcellulose hydrogel must necessarily serve that function. Hence, the cited reference clearly discloses the same mobilizing agent as applicant's claims, and in view of the already disclosed releasing effect of erythromycin, the claimed amount language is deemed to have been necessarily met by prior art formulation.

Claims 10, 12-14, 33, 34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kornman (WO 95/09601) for the reasons of record. See page 8 of the last Office action (mail date: 2/27/2004).

Kornman explicitly discloses a gel composition that contains azithromycin, 70 wt% glycerol monooleate, and 5 wt% hydroxypropyl methylcellulose (p. 9, Example 1).

Kornman's gel would necessarily function as claimed by applicant. Applicant's specification discloses methylcellulose gel and "other organic gels" as suitable mobilizing agents (p. 6, lines 15-24). Clearly, the hydroxypropyl methylcellulose containing gel by Kornman et al. is within the metes and bounds of applicant's mobilizing agent feature. The claims are thereby anticipated.

Applicant's arguments relative hereto have been given due consideration but they were deemed unpersuasive. Applicant argues that the cited reference does not

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show use of an organic gel in an amount sufficient to enable a macrolide antibiotic to penetrate into musculoskeletal soft tissue.” The Examiner cannot agree. First, applicant’s originally filed disclosure is devoid of any teaching that specifies how much of the gel ingredient hydroxypropyl methylcellulose should be present to provide such penetrating effect. Hence applicant’s own disclosure suggests a broad range of such amount in the absence of specified criticality. Second, the cited reference here discloses 5 wt% hydroxypropyl methylcellulose and 70 wt% glycerol monooleate gel composition, with 25 wt% azithromycin. Given the same exact ingredients and a typical amount of the gel formulation ingredients, the burden is shifted to applicant to show that the prior art composition, which contains the same components as the claimed invention, do not in fact possess the properties or features required in the claimed invention.

Grounds of rejection from the previous Office action, which are not maintained here, are hereby withdrawn in view of applicant’s claim amendments of 8/30/2004.

Claims 1-3, 8-9, 18-32 and 38-42 are allowed.

Claims 15-17 and 35-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

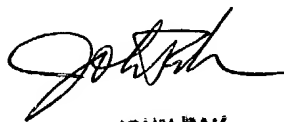
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

  
**JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600**